REMARKS

In the Office Action dated June 23, 2008, the Examiner rejected claims 1-11, 15-19, and 21.

1. Amendements to the Claims

Claim 21 has been amended to be consistent with claims 1 and 2. Support for this amendment is found in the Examples, as discussed below.

2. 35 U.S.C. §112 New Matter

The Examiner rejects claims 1-11, 15-19, and 21 as lacking sufficient written description. The Examiner states that "[n]o basis or support is found in the present specification for phosphatidyl-L-serine sodium salt having a purity of over 95%." (Office Action, page 2). Applicants respectfully submit that the sodium salt is implicitly disclosed in the process. As one of skill in the art would recognize, all the examples describe the initial dissolution of serine in the presence of sodium acetate trihydrate and calcium hydrochloride trihydrate. Subsequently, the phophatidyl-choline starting material is added with the PLD, resulting in a mixture of the calcium and sodium salts of phosphatidyl-L-serine. During the final precipitation, an excess of sodium acetate (4.5 M) is added in water an ethanol. (Specification, [0030], [0040], [0049], and [0058]). At this final precipitation step, the mixture of the calcium and sodium salts of phosphatidyl serine is converted to only the sodium salt of phosphatidyl serine. Due to the binding affinity of the calcium for acetate, the sodium from the sodium acetate replaces the calcium on the phosphatidyl serine product. Specifically, the calcium affinity for the acetate ion is higher than sodium's affinity for the acetate. This is because the protonated amino group of the phosphatidyl serine (which is α to the carboxyl), withdraws electron density from the carboxyl of phosphatidyl serine, decreasing the affinity for Ca^{2+}. Thus, Applicants submit that the product as described in the Specification implicitly discloses the sodium salt of phosphatidyl-L-serine, and that the resultant product, by the nature of the chemical reaction, is very pure.

3. 35 U.S.C. §112 Indefiniteness

The Examiner rejects claims 5-6 and 21 as indefinite. The Examiner states that claims 5-6 appear internally inconsistent in being directed to a sodium salt, yet the RI moiety is hydroxyl. Applicants submit that the claim is definite. The claims recite a phosphtidyl-serine sodium salt of the phostphatidyl-serine formula presented in formula I. Thus, the claim does not encompass the phosphatidyl-serine of formula I, it does encompass the sodium salt of formula I. Thus, Applicants submit that the claim is definite and clear.

The Examiner states that claim 21 is "indefinite and confusing, and lacks antecedent basis in the recitation of the preamble phosphatidyl-L-serine and in the subsequent recitation of said phosphatidylcholine reactant is completely convereted to phosphatidyl-L-serine, since claims 1 and 2 are directed to a phostphatidyl-L-serine sodium salt." Applicants have amended claim 21.

4. 35 U.S.C. §102/103

The Examiner rejects claims 5-11and 15-19 as anticipated by Sakai. The Examiner states that Sakai discloses a phosphatidyl-L-serine composition which contains a phosphtidyl-L-serine sodium salt compositions having the same structure as claimed and which is recognized to be useful as a food additive or a pharmaceutical for oral administration. . . . Inasmuch as sodium phosphate buffer is used, phosphtidyl-L-serine sodium salt is present at least to some extent." (Office Action, page 4). Applicants respectfully disagree.

Sakai does not disclose a composition having a purity of 95% or more, and with a degree of peroxidation of less than 5. In particular, the Declaration of Dr. Menon describes that not only was the product of the Sakai process not as pure, the Sakai process did not work as described. Menon Declaration, pages 2-3. Thus, Sakai not only does not anticipate each element of the claimed invention (i.e., the purity and degree of peroxidation) it is not an enabling reference.

The Examiner further rejects claims 1-11, 15-20, and 21 as being obvious in light of Sakai, taken with De Ferra and Horrobin, Puricelli, Chemical Land21, and Kurihara et al..

The Examiner states that "the composition claims are directed to a composition containing undefined amounts of this product, and thus cannot be readily distinguished over the compositions disclosed by Sakai. Therefore, applicants' arguments directed to the differences in purity are not relevant to the claimed invention." (Office Action, page 7). Applicants respectfully disagree that the purity of the product is "not relevant."

As discussed above, the Sakai reference is not enabling prior art. Furthermore, none of the references disclose a 95% pure phosphatidyl-L-serine sodium salt having a degree of peroxidation of less than 5. The Specification discloses that the product of the disclosed method is 95% pure phosphatidyl-L-serine having a degree of peroxidation of less than 5. One of skill would understand from the disclosed method that all of the phosphatidyl-L-serine product would be in the sodium salt form. None of the prior art references disclose a composition with these three characteristics.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Conclusion

In view of the above remarks, it is believed that claims are allowable.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson Reg. No. 30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

By _____

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